K122123 (1/2)

DePuy Mitek Inc. never stop moving

PRODUCT: INTRAFIX® PEEK Tapered Screw
SUBMISSION DATE: July 17, 2012
SUBMISSION TYPE: TRADITIONAL

ATTACHMENT 1

510(k) SUMMARY - INTRAFIX PEEK TAPERED SCREW

OCT 2 2012

SUBMITTER'S NAME AND ADDRESS

DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

CONTACT PERSON

Julie Vafides
Regulatory Affairs Specialist II
DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

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DATE PREPARED	7/17/2012

NAME OF MEDICAL DEVICE
COMMON CLASSIFICATION NAME
Fastener, Fixation, Nondegradable, Soft Tissue

PROPRIETARY NAME
INTRAFIX® PEEK Tapered Screw

SUBSTANTIAL EQUIVALENCE
INTRAFIX PEEK Tapered Screws are substantially equivalent to the following devices.

- INTRAFIX® Tapered Screws (K983560) – Modified Device
  (previously known as Intratunnel Fixation Fastener, cleared January 28, 1999)
- K063577 – Femoral INTRAFIX® Screw and Sheath

FDA PRODUCT CODE
MBI

DEVICE CLASSIFICATION
This type of **fixation screw** was originally classified as a **Class II** medical device by the **Orthopedic Review Panel,** regulated as 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.

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DEVICE DESCRIPTION

The proposed INTRAFIX System consists of two components, a non-absorbable INTRAFIX Expansion Sheath and a non-absorbable INTRAFIX Expansion Screw. Also included within the system is the instrumentation to place devices and establish the tunnel. The device functions by establishing the tunnel and placing the expansion Sheath into the tunnel by the use of Sheath Inserter. This is followed by screwing an Expansion Screw into the Sheath expanding the Sheath which compresses the graft against the tunnel and creating fixation.

INDICATIONS FOR USE

The DePuy Mitek Tibial Tapered Screw and Tibial Sheath are indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

TECHNOLOGICAL CHARACTERSTICS

The proposed INTRAFIX PEEK Tapered Screws are similar in design and indication to the predicate INTRAFIX Tapered Screws. The proposed INTRAFIX PEEK Tapered Screws are manufactured out of PEEK (polyetheretherketone), a non-absorbable radiolucent high strength thermoplastic material. The proposed PEEK material is a well-known material with a long and safe use in medical devices. A similar PEEK material is used in manufacturing the screw component of the predicate Femoral INTRAFIX Screw and Sheath (K063577).

NONCLINICAL TESTING

Verification activities, such as, Torque Capability and Pullout Strength testing were performed on the implant and its predicate device.

SAFETY AND PERFORMANCE

Results of performance and safety testing have demonstrated that the modified device is substantially equivalent to the predicate devices.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed INTRAFIX PEEK Tapered Screws have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek Incorporated, a johnson and johnson company
% Ms. Julie Vafides
Regulatory Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

OCT 2 2012

Re: K122123
Trade/Device Name: INTRAFIX® PEEK Tapered Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 17, 2012
Received: July 18, 2012

Dear Ms. Vafides:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

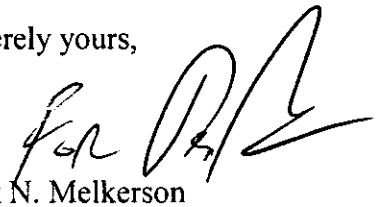
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122123 (1/1)

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PRODUCT: INTRAFIX® PEEK Tapered Screw
SUBMISSION DATE: July 17, 2012
SUBMISSION TYPE: TRADITIONAL

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: INTRAFIX® PEEK Tapered Screw

Indications for Use: The DePuy Mitek Tibial Tapered Screw and Tibial Sheath are indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of _____

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122123